Washington, DC — Yesterday, Congressman Joe Sestak (D-PA) voted for passage of the bi-partisan FDA Amendments bill to respond to the growing concern in recent years about drug safety. — "This new FDA legislation will help protect Americans by imposing more stringent drug safety policies and requirements," said Congressman Sestak, "The provisions of the bill represent the most sweeping safety and regulatory changes to the agency in years, and add critical surveillance and safety requirements for drugs after they have been approved and marketed."

The FDA Amendments bill reauthorizes the prescription drug user fee for five years and increases the user fee in order to allow FDA to approve life-saving drugs more quickly, while creating a new FDA program to monitor the safety of drugs after they enter the market. The bill also includes other measures to enhance drug safety, including increasing the penalties for drug companies that violate safety standards and imposing strict conflict-of-interest provisions to ensure FDA is not making decisions based on the personal financial interests of those serving on advisory panels.

Promoting Drug Safety
Under the bill, FDA would establish a surveillance system to track the adverse effects of drugs on the market. Additionally, based on this surveillance, a drug on the market could then be subject to follow-up FDA studies, at the discretion of the agency. In the case of some riskier drugs, there would be regulations limiting prescribing authority to physicians with special training.

Fine Increases for violating FDA safety standards.
Under this bill, prescription drug and medical device companies would be subject to a fine up to $250,000 per violation of FDA safety regulations, and a fine up to $1 million for several violations adjudicated in a single proceeding. If companies are notified of violations but continue to defy regulations, they would be subject to a fine up to $1 million for any 30-day period and a fine up to $10 million for several violations adjudicated in a single proceeding.

Penalties for false or misleading advertising
The bill imposes a maximum penalty of $250,000 for a first offense in any three-year period of a "false or misleading ad" in direct-to-consumer advertising for prescription drugs. There would be a penalty of up to $500,000 for each subsequent offense.

Publicly available databases on clinical trials
Two publicly available databases, accessible over the Internet, will be created on clinical trials of new prescription drugs seeking FDA approval. The first database would include a registry of ongoing clinical trials, and the second would post the results of clinical trials.

Reducing Conflict of Interest
As part of its drug safety provisions, the bill also includes stricter conflict of interest provisions – to better ensure that the FDA is acting on information that is truly objective and is not making decisions based on the personal financial interests of those serving on advisory committees.

Specifically, the bill requires all individuals under consideration for appointment to serve on an advisory committee to disclose all financial interests that would be affected by the advisory committee's actions. FDA shall determine the aggregate percentage of waivers of conflicts of interest provided in FY 2007. The bill then requires FDA to decrease the number of waivers by five percent each year for the next five years.

Increases Prescription Drug User Fees
The bill reauthorizes for five years the Prescription Drug User Fee Act– a law that allows the FDA to charge fees to drug companies to expedite the agency's review of drug approval applications. It significantly increases the user fees, which will be used to increase staffing and provide faster approval of drugs.

Encourages Development of Pediatric Drugs and Devices
The bill includes several provisions to encourage the development of pediatric drugs and devices to make more new drugs available to children, who typically represent a much smaller pool of likely consumers than adults.

Born and raised in Delaware County, former 3-star Admiral Joe Sestak served in the Navy for 31 years and now serves as the Representative from the 7th District of Pennsylvania. He led a series of operational commands at sea, including Commander of an aircraft carrier battle group of 30 U.S. and allied ships with over 15,000 sailors and 100 aircraft that conducted operations in Afghanistan and Iraq. After 9/11, Joe was the first Director of "Deep Blue," the Navy's anti-terrorism unit that established strategic and operations policies for the "Global War on Terrorism." He served as President Clinton's Director for Defense Policy at the National Security Council in the White House, and holds a Ph.D. in Political Economy and Government from Harvard University. According to the office of the House Historian, Joe is the highest-ranking former military officer ever elected to the U.S. House of Representatives.